

Notice of Allowability

Application No.

10/052,905

Applicant(s)

SCHWENDNER ET AL.

Examiner

Frederick F. Krass

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

☒ This communication is responsive to the amendment dated January 20, 2004.

☒ The allowed claim(s) is/are 1,4-8,11,12,15-18 and 21-34.

☒ The drawings filed on 02 November 2001 are accepted by the Examiner.

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

☐ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 12-23-03

☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 4-16-04

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____



Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Frank Mycroft on April 16, 2004.

1) Page 1 of the specification, line 9, between "2000" and the period there has been inserted --- , now USP 6,355,628---

2) Page 9 of the specification, line 26, between the first occurrence of "1999" and the semicolon there has been inserted --- , now abandoned ---

3) Page 9 of the specification, line 27, between "1998" and the period there has been inserted --- , now USP 6,153,585 ---

4) Claim 1, last line on page 2 of the response, and claim 17, last line on page 6 of the response, in each instance "and the" has been replaced by --- or ---

Art Unit: 1614

5) Claims 15 and 16, first line of each claim, in each instance "12" has been changed to --- 11 ---

6) Claims 21 and 22, first line of each claim, in each instance "18" has been changed to --- 17 ---

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The examiner agrees with Applicant's response substantially as written and adds the following only for emphasis. As discussed in the response, Figures 1 and 2 demonstrate that the combination of a methoxybenzene-substituted perfluorobenzenesulfonamide compound and either paclitaxel or gemcitabine provides synergistic activity. This is unexpected in view of the prior art, which does not exemplify any combination of a particular anticancer agent with a perfluorobenzenesulfonamide (e.g. in the form of a working example of discrete preferred embodiment). Accordingly, no direction is provided for selecting paclitaxel (or gemcitabine); instead, one must engage in substantial "picking and choosing" from a list of divergent candidates at col. 20, lines 6-15 of USP 6,482,860. The results are even more unexpected given the fact that paclitaxel and the claimed perfluorobenzenesulfonamides are both microtubule inhibitors (see USP 6,482,860 at col. 18, lines 15-21). Synergism is unexpected *per se*, but is even more so where both anticancer agents work by the same mechanism.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;
Tuesday: 10-6:30PM;
Wednesday: off;
Thursday: 10-6:30PM; and
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Marianne, can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Application/Control Number: 10/052,905

Page 5

Art Unit: 1614

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'F. Krass', with a long horizontal flourish extending to the right.